IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

MEDPOINTE HEALTHCARE INC., Plaintiff, vs. APOTEX INC. and APOTEX CORP., Defendants.	Civil Action No. 06-164-SLR

PLAINTIFF'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO STRIKE APOTEX'S JURY DEMAND, STRIKE APOTEX'S AFFIRMATIVE DEFENSE OF UNENFORCEABILITY, DISMISS APOTEX'S COUNTERCLAIM OF UNENFORCEABILITY, AND STRIKE APOTEX'S AFFIRMATIVE DEFENSE OF MISUSE

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INTRODUCTION

Plaintiff MedPointe Healthcare Inc. ("MedPointe") brought this suit to prevent Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") from marketing a generic copy of its Astelin® Nasal Spray product prior to expiration of United States Patent No. 5,164,194 ("the '194 patent"). Astelin® Nasal Spray was the first, and remains the only, intranasal antihistamine approved by the United States Food and Drug Administration ("FDA"). Moreover, Astelin® Nasal Spray is the only prescription antihistamine approved by the FDA to treat both allergic and non-allergic rhinitis. The '194 patent issued on November 17, 1992 to Asta Pharma AG as assignee. Since August 16, 2002, MedPointe has been, and continues to be, the sole owner of the '194 patent and the sole owner of the right to sue and to recover for any infringement of that patent. MedPointe's '194 patent and related exclusivities are, at present, set to expire on May 1, 2011.

Apotex apparently concedes that the proposed generic product for which it submitted Abbreviated New Drug Application ("ANDA") No. 77-954 ("the Generic Product") will infringe the '194 patent, failing to raise noninfringement in its Answer to Plaintiff's Amended Complaint, Affirmative Defenses and Counterclaims ("Answer and Counterclaims") (D.I. 11). Unwilling to delay introduction of its Generic Product until expiration of the '194 patent, Apotex raised several affirmative defenses and declaratory-judgment counterclaims regarding the validity and enforceability of the '194 patent. Among these defenses and counterclaims, Apotex asserts that the '194 patent has been misused and is unenforceable.

But Apotex fails to plead its unenforceability defense and counterclaim with the specificity that the Federal Rules of Civil Procedure require for claims and defenses of this nature. In addition, the alleged factual bases for Apotex's patent misuse defense are acts either sanctioned by the Patent Act or immune from liability under the *Noerr-Pennington* doctrine.

Further, Apotex improperly makes a jury demand, when this action raises no issues that are triable by jury as a matter of right. Accordingly, MedPointe respectfully requests that the Court strike Apotex's jury demand, strike Apotex's affirmative defenses of misuse and unenforceability, and dismiss Apotex's declaratory judgment counterclaims to the extent that they seek to have the '194 patent declared unenforceable.

NATURE AND STAGE OF THE PROCEEDINGS AND STATEMENT OF FACTS

On January 27, 2006, MedPointe received notice that Apotex had submitted ANDA No. 77-954 to the FDA, seeking approval to market an infringing copy of MedPointe's drug Astelin® prior to the expiration of the '194 patent. Apotex's ANDA contains an allegation under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '194 patent is invalid, unenforceable and/or will not be infringed by its proposed Generic Product (a "Paragraph IV Certification"). The Hatch-Waxman Act permits generic manufacturers such as Apotex to challenge patent protection for drugs without selling a product and, thereby, incurring the risk of monetary damages. The statutory vehicle for these challenges is 35 U.S.C. § 271(e)(2), which creates a cause of action based on the technically infringing act of submitting an ANDA to the FDA. If the patent owner does not agree with the Paragraph IV certification, the Hatch-Waxman Act gives the patent owner 45 days to file an infringement claim. 21 U.S.C. § 355(j)(5)(B)(iii). The Act specifies that the filing of the infringement suit automatically stays the FDA's approval of the ANDA for 30 months from the date the patentee received notice of the Paragraph IV certification while the parties litigate the infringement claim ("30-month stay"). *Id.*

MedPointe commenced this action against Apotex for infringement of the '194 patent within 45 days of receiving notice of Apotex's Paragraph IV certification – filing a Complaint on March 10, 2006 (D.I. 1) and an Amended Complaint on March 13, 2006 (D.I. 5).

In its Amended Complaint, MedPointe alleged, *inter alia*, that Apotex's submission of its ANDA to the FDA constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2). (Amended Complaint ¶ 20) MedPointe does not allege that Apotex has already engaged in actual, as opposed to technical, infringement of the '194 patent. Because no actual infringement has yet occurred, MedPointe's Amended Complaint requests only prospective injunctive relief and attorney fees, and does not request any monetary relief unless Apotex actually begins selling its copycat product before expiration of the '194 patent, including any extensions. (Amended Complaint ¶ D)

The prospect of actual infringement by Apotex at this time is remote. With a 30-month stay in place, the FDA will not grant final approval of Apotex's Generic Product before July 27, 2008. Unless Apotex breaks the law and markets its Generic Product without FDA approval, it cannot incur any monetary damages based on actual infringement before expiration of the 30-month stay. As a result, no monetary damages are being, or could be, sought in the trial in this action.

Apotex served its Answer and Counterclaims (D.I. 11) on April 14, 2006, raising five affirmative defenses, titled: 1) invalidity, 2) anticipation, 3) obviousness, 4) unenforceability and 5) misuse. Apotex also raised declaratory judgment counterclaims based on each of those defenses, except misuse, and demanded a jury trial on "all issues triable by jury as a matter of right." This motion is being filed concurrently with MedPointe's Reply to Apotex's Counterclaims.

In pleading its unenforceability defense and counterclaim, Apotex alleges that the applicants for the '194 patent made affirmative misrepresentations to the United States Patent and Trademark Office ("PTO"), citing only an article bearing a 1997 copyright date and an Astelin®

Nasal Spray package insert bearing a revision date of May 2003 (D.I. 12) to support their allegations. (Answer and Counterclaim ¶¶ 31-33 and 59-66). However, the U.S. application that led to the '194 patent, which issued in 1992, was filed with the PTO almost a decade earlier in 1988. Apotex also apparently asserts unenforceability as part of its invalidity defense and counterclaim, stating:

> The '194 patent is invalid and/or unenforceable on grounds specified in United States Code, Title 35, including failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

(Answer and Counterclaims ¶¶ 28 and 49).

As demonstrated below, these allegations fail to provide sufficient notice of a cognizable claim for unenforceability. Apotex apparently concedes that it lacks sufficient facts to properly plead unenforceability, stating:

> A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support and further evidentiary support that such acts were done with intent to mislead the PTO and to fraudulently extend patent protection of azelastine.
>
> A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support and further evidentiary support that the foregoing misrepresentations and failure to disclose material prior art as set forth above were done with intent to mislead the PTO.

(respectively, Answer and Counterclaims ¶¶ 33 and 61; Answer and Counterclaims ¶ 62).

Apotex also apparently asserts unenforceability as part of its misuse defense, stating:

> The '194 patent is invalid and obtained fraudulently and by inequitable conduct. MedPointe submitted the '194 patent to the FDA to be listed among Approved Drug Products With Therapeutic Equivalence Evaluation (also known as the "Orange Book") as covering azelastine hydrochloride. MedPointe has also commenced this infringement action against Apotex. MedPointe's

> efforts to enforce the '194 patent, by infringement suits and by listing that patent in the Orange Book, constitutes patent misuse.

(Answer and Counterclaims ¶ 34).

As demonstrated below, this allegation fails to provide sufficient notice of a cognizable claim for either patent misuse or unenforceability. Moreover, Apotex is not entitled to a jury trial. Accordingly, Apotex's jury demand should be stricken, Apotex's affirmative defenses of misuse and unenforceability should be stricken, and Apotex's declaratory judgment counterclaims should be dismissed to the extent that they seek to have the '194 patent declared unenforceable.

SUMMARY OF THE ARGUMENT

The Court should strike Apotex's jury demand for the following reasons:

1. There is no statutorily created right to a jury trial in § 271(e)(2) actions. In fact, the express statutory language provides for trial of all § 271(e)(2) actions to the court.

2. No constitutional right to a jury trial is implicated in a § 271(e)(2) action. Under the Seventh Amendment, there is no right to a jury trial if the underlying action is inherently equitable and the relief sought is entirely equitable. *See, e.g., Tull v. United States*, 481 U.S. 412 (1987); *Tegal Corp. v. Tokyo Electron Am., Inc.*, 257 F.3d 1331 (Fed. Cir. 2001). In § 271(e)(2) actions, both the underlying action and the relief sought are entirely equitable. *See, e.g., Pfizer Inc. v. Novopharm Ltd.*, No. 00 C 1475, 2001 WL 477163 at *3, *4 (N.D. Ill. May 3, 2001)[1] (reasoning that a § 271(e)(2) action is "a controversy of recent vintage created by Congress for the specific purpose of posturing drug claims for adjudication before actual

[1] Unreported opinions are reproduced in the "Compendium Of Unreported Opinions In Plaintiffs' Opening Brief in Support of its Motion to Strike Apotex's Jury Demand, Strike Apotex's Affirmative Defense of Unenforceability, Dismiss Apotex's Counterclaim of Unenforceability, and Strike Apotex's Affirmative Defense of Misuse" filed herewith.

infringement occurs. As such, it is inherently equitable . . . ," and stating that "the statute expressly precludes the plaintiff from recovering damages except in the rare situation where the defendant has already engaged in the commercial manufacture, use, or sale of the drug without FDA approval.").

3. The assertion of counterclaims for a declaratory judgment of invalidity or unenforceability does not entitle the defendant in a § 271(e)(2) action to a jury trial. *In re Impax Labs.*, No. 815, 2006 WL 751877 (Fed. Cir. Mar. 2, 2006) (holding no right to a jury where challenger sought declaratory judgment of invalidity, noninfringement, and unenforceability and the patentee sought injunctive relief only). Declaratory judgment counterclaims cannot alter the underlying equitable nature of a § 271(e)(2) action; if the underlying action is equitable, the declaratory judgment counterclaims are also considered equitable. *See In re Lockwood*, 50 F.3d 966, 973 (Fed. Cir. 1995), *vacated by* 515 U.S. 1182 (1995), and *aff'd*, 107 F.3d 1565 (Fed. Cir. 1997) ("declaratory judgment actions, are, for Seventh Amendment purposes, only as legal or equitable in nature as the controversies on which they are founded"); *Kao Corp. v. Unilever U.S., Inc.*, No. 01-680-SLR, 2003 WL 1905635 at *3 (D. Del. April 17, 2003) ("[A]n alleged infringer has no entitlement to a trial by jury by virtue of pleading counterclaims asserting noninfringement and invalidity, claims which are equitable in nature with no attendant right to damages.").

4. Decisions of the Federal Circuit and of many district courts, including the District of Delaware, have confirmed that there is no statutory or constitutional jury trial right in § 271(e)(2) actions, which are inherently equitable and in which only equitable relief is sought. *See, e.g., Tegal*, 257 F.3d at 1341 (Fed. Cir. 2001) (concluding that because the patentee "sought only an injunction, a purely equitable remedy . . . . there is no doubt that neither party had a right

to a jury"); *Allergan, Inc. v. Alcon, Inc.*, No. 04-968-GMS, 2005 WL 3971928 (D. Del. July 22, 2005) (holding no right to jury trial in § 271(e)(2) action because patentee was entitled to only injunctive relief); *Glaxo Group Ltd. v. Apotex, Inc.*, No. 00 C 5791, 2001 WL 1246628 at *5 (N.D. Ill. Oct. 16, 2001) (holding "that an action brought pursuant to § 271(e)(2) is inherently equitable in nature, and that the remedies are limited accordingly. Therefore . . . neither plaintiff nor defendant is entitled to a jury trial on any of the issues raised in this case").

In addition, the Court should strike Apotex's affirmative defense of unenforceability and dismiss its counterclaims to the extent that they seek to have the '194 patent declared unenforceable for the following reasons:

5. Apotex fails to meet the heightened pleading requirement of Federal Rule of Civil Procedure 9(b), which applies to unenforceability defenses and counterclaims. *See* Fed. R. Civ. P. 9(b) ("[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity."); *Agere Sys. Guardian Corp. v. Proxim, Inc.*, 190 F. Supp. 2d 726, 733-34 (D. Del. 2002) ("in pleading an inequitable conduct claim, a party cannot merely rely on vague allegations that broadly recite the elements of fraud, but instead must either specify the time, place, and content of any alleged misrepresentations made to the PTO or otherwise 'give the defendant[] notice of the precise misconduct alleged.'" (citations omitted). This includes identifying any allegedly material prior art that the party contends was not disclosed to the PTO. *EMC Corp. v. Storage Tech. Corp.*, 921 F. Supp. 1261, 1263 (D. Del. 1996) (deeming inequitable conduct counterclaim that failed to disclose the relevant prior art insufficient under Rule 9(b)).

6. An improperly pled unenforceability counterclaim is properly dismissed pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted.

See, e.g., Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 783 n.5 (4th Cir. 1999) ("lack of compliance with Rule 9(b)'s pleading requirements is treated as a failure to state a claim under Rule 12(b)(6)"). An improperly pled unenforceability defense is properly stricken pursuant to Fed. R. Civ. P. 12(f) as insufficient as a matter of law. *See, e.g., France Telecom S.A. v. Novell, Inc.*, No. 102-437-GMS, 2002 WL 31355255, at *1 (D. Del. Oct. 17, 2002) (motion to strike will be denied only "if the defense is sufficient under the law").

Finally, the Court should strike Apotex's affirmative defense of patent misuse for the following reasons:

7. MedPointe's action of filing suit for patent infringement of the '194 patent is specifically sanctioned by the Patent Act, 35 U.S.C. § 271(d)(3) (it shall not constitute patent misuse to enforce a patent infringement claim). Similarly, the listing of the '194 patent in the Orange Book is immune from liability under the *Noerr-Pennington* doctrine. *See Cheminor Drugs, Ltd. v. Ethyl Corp.*, 993 F. Supp. 271, 278 (D.N.J. 1998), *aff'd* 168 F.3d 119 (3d Cir. 1999), *cert. denied,* 528 U.S. 871 (1999) (use of governmental process is presumptively immune from liability unless it can be shown to be a "sham.") Apotex, however, does not allege that the '194 patent was improperly listed in the Orange Book. Accordingly, Apotex's misuse defense is insufficient as a matter of law, and is properly stricken pursuant to Fed. R. Civ. P. 12(f).

For all these reasons, as explained in more detail below, MedPointe respectfully requests that the Court grant its motion to strike Apotex's jury demand, strike Apotex's affirmative defenses of misuse and unenforceability, and dismiss Apotex's declaratory judgment counterclaims to the extent that they seek to have the '194 patent declared unenforceable.

ARGUMENT

I. Apotex's Jury Demand Should Be Stricken

The Hatch-Waxman Act created a cause of action that permits manufacturers of generic drugs to challenge the validity and scope of patents without incurring the risk of monetary damages for infringement. Under 35 U.S.C. § 271(e)(2), the act of submitting an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") is a technical act of infringement that permits a patentee to file suit against the entity that submitted the ANDA, despite the absence of actual infringement. In a typical § 271(e)(2) action, the patentee is statutorily prohibited from obtaining damages because there is no actual infringement, and therefore seeks only prospective injunctive relief. The plain language of the statute precludes the right to a jury trial in these cases. The entirely equitable nature of a § 271(e)(2) action and of the relief sought also renders the Seventh Amendment right to jury trial inapplicable. Neither party to a § 271(e)(2) action, therefore, has the right to a jury trial. Accordingly, Apotex's jury demand should be stricken.

A. There Is No Statutorily Created Right To A Jury Trial In 35 U.S.C. § 271(e)(2) Actions

The plain language of 35 U.S.C. § 271(e) establishes that the statute provides only equitable, not legal remedies. The statute provides that, in the event the court finds that Apotex's ANDA filing constitutes infringement,

> (A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of expiration of the patent which has been infringed,
>
> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary product, and

> (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.
>
> The remedies provided by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

35 U.S.C. § 271(e)(4).

The plain language of the statute nowhere confers the right to a jury trial on the parties to 35 U.S.C. § 271(e)(2) actions. To the contrary, 35 U.S.C. § 271(e)(4) states explicitly that these remedies "are the only remedies which may be granted *by a court* for an act of infringement described in paragraph (2), except that *a court* may award attorney fees under section 285." 35 U.S.C. § 271(e)(4)) (emphasis added). As demonstrated in Section I.C., *infra*, the vast majority of courts have adopted this interpretation of the statute.

B. There Is No Seventh Amendment Right To A Jury Trial In 35 U.S.C. § 271(e)(2) Actions

No constitutional right to a jury trial is implicated in § 271(e)(2) actions. The Seventh Amendment provides that in "[s]uits at common law . . . the right of trial by jury shall be preserved." U.S. Const. Amend. VII. Supreme Court precedent establishes that if both the underlying action and the relief sought are equitable, there is no Seventh Amendment right to a jury trial. *See, e.g.*, *Tull v. United States*, 481 U.S. 412, 417-18 (1987) ("[T]hose actions that are analogous to 18th-century cases tried in courts of equity or admiralty do not require a jury trial. . . . To determine whether a statutory action is more similar to cases that were tried in courts of law than to suits tried in courts of equity or admiralty, the Court must examine both the nature of the action and of the remedy sought."). In suits brought under 35 U.S.C. § 271(e)(2), because both the underlying action and the remedies sought are entirely equitable, no Seventh

Amendment jury trial right attaches. The assertion of counterclaims for invalidity and noninfringement in 35 U.S.C. § 271(e)(2) actions has no effect on the Seventh Amendment analysis and does not entitle either party to a jury trial.

1. There Is No Seventh Amendment Right To A Jury Trial If Both The Underlying Action And The Remedy Sought Are Equitable

The Supreme Court has set out a two-part framework for courts to consider in assessing the Seventh Amendment right to a jury trial in statutory actions: courts must evaluate both the nature of the underlying action, and, more importantly, the nature of the remedy sought. *See Tull*, 481 U.S. at 417, 421; *see also Tegal Corp. v. Tokyo Electron Am., Inc.*, 257 F.3d 1331, 1339 (Fed. Cir. 2001) ("the Supreme Court has repeatedly taught . . . that the nature of the remedy is more important than that of the action."). In examining the nature of the underlying action, courts should "compare the statutory action to 18th-century actions brought in the courts of England prior to the merger of the courts of law and equity." *Tull*, 481 U.S. at 417. After determining whether the action more closely resembles one that would have been brought at law or at equity in 18th-century England, courts should examine "the remedy sought and determine whether it is legal or equitable in nature." *Id.*

2. 35 U.S.C. § 271(e)(2) Actions Are Entirely Equitable

Application of Federal Circuit precedent to the analysis of the nature of 35 U.S.C. § 271(e)(2) actions compels the conclusion that these actions are entirely equitable for purposes of the Seventh Amendment. In *Tegal*, the Federal Circuit found that a patentee in 18th-century England could have brought an infringement suit either at law or at equity. *Tegal*, 257 F.3d at 1340. If the patentee sought damages, it would bring the suit at law; if it sought injunctive relief, it would bring the suit at equity.

An action under 35 U.S.C. § 271(e)(2), in which the patentee seeks solely prospective injunctive relief, could only have been brought at equity in 18th-century England. *See id.* ("[G]iven Tegal's interest only in an injunction, it is clear that Tegal would have needed, in eighteenth century England, to bring its case in a court of equity."). Because 35 U.S.C. § 271(e)(2) actions are not predicated on actual infringement, the actions are inherently equitable. *See, e.g., Sanofi-Synthelabo v. Apotex, Inc.*, No. 02 Civ. 2255, 2002 U.S. Dist. LEXIS 15345 at *20 (S.D.N.Y. Aug. 14, 2002) (concluding that the patentee bringing suit under 35 U.S.C. § 271(e)(2) could not choose whether to proceed in law or in equity but must proceed in law: the patentee "could only seek to prevent future infringement – an indisputably equitable remedy"); *Pfizer Inc. v. Novopharm Ltd.*, No. 00 C 1475, 2001 WL 477163 at *4 (N.D. Ill. May 3, 2001) (reasoning that a § 271(e)(2) action is "a controversy of recent vintage created by Congress for the specific purpose of posturing drug claims for adjudication before actual infringement occurs. As such, it is inherently equitable"); *Glaxo Group Ltd. v. Apotex, Inc.*, No. 00 C 5791, 2001 WL 1246628 at *5 (N.D. Ill. Oct. 16, 2001) ("[A]n action brought pursuant to § 271(e)(2) is inherently equitable in nature....").

Under the first prong of the Seventh Amendment analysis, MedPointe's 35 U.S.C. § 271(e)(2) action is equitable.

3. The Relief Sought Is Entirely Equitable

The second and more important prong of the Seventh Amendment analysis requires evaluation of the relief sought. The plain language of 35 U.S.C. § 271(e) precludes patentees from obtaining damages based on the statutorily created, artificially infringing act of filing an ANDA. Damages are available only if the defendant has engaged in the atypical act of marketing the infringing drug without FDA approval. *See* 35 U.S.C. § 271(e)(4)(C); *Pfizer*, 2001 WL 477163 at *3 ("the statute expressly precludes the plaintiff from recovering damages

except in the rare situation where the defendant has already engaged in the commercial manufacture, use, or sale of the drug without FDA approval"); *Biovail Labs., Inc. v. Torpharm, Inc.*, No. 01 C 9008, 2002 U.S. Dist. LEXIS 13502, at *6-*7 (N.D. Ill. July 23, 2002) (concluding that the statute "precludes damages except when a defendant has already engaged in the commercial manufacture, use, or sale of the drug without FDA approval").

The chance that the defendant in a 35 U.S.C. § 271(e)(4)(C) action might at some future time engage in actual infringing activity does not entitle the defendant to a jury trial. See *Biovail*, 2002 U.S. Dist. LEXIS 13502 at *8-*9 (refusing to grant a jury trial despite the "small chance" that Apotex's ANDA would obtain approval prior to trial or that it would begin marketing the generic drug before trial, and noting that "at this point in the proceedings, none of this has occurred"); *Sanofi-Synthelabo*, 2002 U.S. Dist. LEXIS 15345, at *19-*20 (refusing to grant a jury trial, or to deny the motion to strike the jury demand as premature, despite the possibility that the defendant might engage in actual infringing activities prior to the resolution of the case).

MedPointe does not allege any infringement other than Apotex's ANDA filing, for which MedPointe can obtain only prospective injunctive relief. Apotex is not subject to any reasonably foreseeable exposure to liability for damages. Apotex's ability to obtain approval or market its product is restricted not only by the outcome of the present case but also by a 30-month stay of FDA approval of the Generic Product. FDA regulations prohibit Apotex from launching prior to expiration of the stay on July 27, 2008, unless this Court finds the '194 patent invalid or unenforceable before that date. As a result, Apotex's hypothetical exposure to damages is far too speculative to entitle it to a jury trial.

4. Apotex's Counterclaims Do Not Give Rise To A Seventh Amendment Jury Trial Right

The assertion of counterclaims for declaratory judgments of invalidity or unenforceability do not entitle defendants to jury trials in 35 U.S.C. § 271(e)(2) actions. *See In re Impax Labs.*, No. 815, 2006 WL 751877 (Fed. Cir. Mar. 2, 2006) (holding no right to a jury where challenger sought declaratory judgment of invalidity, noninfringement, and unenforceability and the patentee sought injunctive relief only). Declaratory judgment actions have no legal or equitable character independent of the underlying action, and they cannot alter the Seventh Amendment two-pronged analysis. *See Gulfstream Aerospace Corp. v. Macayamas Corp.*, 485 U.S. 271, 284 (1988) ("Actions for declaratory judgments are neither legal nor equitable"); *In re Lockwood*, 50 F.3d 966, 973 (Fed. Cir. 1995), *vacated by* 515 U.S. 1182 (1995), and *aff'd*, 107 F.3d 1565 (Fed. Cir. 1997) ("[D]eclaratory judgment actions, are, for Seventh Amendment purposes, only as legal or equitable in nature as the controversies on which they are founded.").

If the patentee has chosen to seek only equitable relief, the defendant has no right to a jury trial. *See, e.g., Kao Corp. v. Unilever U.S., Inc.*, No. 01-680-SLR, 2003 WL 1905635 at *3 (D. Del. Apr. 17, 2003) ("[A]n alleged infringer has no entitlement to a trial by jury by virtue of pleading counterclaims asserting noninfringement and invalidity, claims which are equitable in nature with no attendant right to damages."); *Technology Licensing Corp. v. Gennum Corp.*, No. 3:01-cv-4204, 2004 WL 1274391 (N.D. Cal. Apr. 9, 2004), (striking jury demand, where patentee sought only prospective injunctive relief, despite the pendency of a third-party complaint for declaratory judgment of invalidity and noninfringement). Here, MedPointe seeks only prospective injunctive relief. Accordingly, Apotex is not entitled to a jury trial.

C. The Courts Have Found No Right To A Jury Trial In 35 U.S.C. § 271(e)(2)) Actions

1. The Majority of District Courts Have Found No Right To A Jury In 35 U.S.C. § 271(e)(2) Actions

Based on both the plain language of the statute and the controlling Seventh Amendment precedent discussed herein, *supra*, most district courts that have considered the issue, including the District of Delaware, have found that there is no statutory or constitutional right to a jury trial in § 271(e)(2) actions. *See, e.g., Allergan, Inc. v. Alcon, Inc.*, No. 04-968-GMS, 2005 WL 3971928, at *1 (D. Del. July 22, 2005) ("'The nature of the underlying controversy is entirely equitable, involving only a controversy whether future acts should be enjoined,' and there is no right to a jury trial in this case."); *Sanofi-Synthelabo*, 2002 U.S. Dist. LEXIS 15345, at *7 ("There is no question that Sanofi has no right to a jury trial on its claims pursuant to § 271(e)(2)...."); *Pfizer*, 2001 WL 477163, at *5 ("Pfizer admittedly has no right to a jury trial on its equitable claims for relief under § 271(e)(2)"); *Glaxo Group Ltd. v. Dr. Reddy's Labs., Ltd.*, No. 01-4066-JLL, at *3 (D.N.J. June 5, 2003) ("A plain reading of Section 271(e)(1) does not support a right to a jury trial"); *Purdue Pharma L.P. v. Endo Pharms., Inc.*, No. 00 Civ. 8029, at *3 (S.D.N.Y. Dec. 10, 2002) ("The statute specifically states that 'the court' shall award any appropriate injunctive relief. Here, Purdue has specifically given up its right to seek monetary damages. In these circumstances, there is no right to a jury in ANDA-based infringement actions") (internal citations omitted). *See also Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (35 U.S.C. § 271(e)(2) provides "patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity").

Tegal and *Lockwood*, *supra,* pp. 12-13, provide the analytical framework for additional decisions holding that the assertion of invalidity or noninfringement counterclaims in

35 U.S.C. § 271(e)(2) actions does not entitle the defendant to a jury trial under the Seventh Amendment. *See, e.g.*, *Glaxo Group Ltd. v. Apotex, Inc.*, 2001 WL 1246628 (granting plaintiff's motion to strike Apotex's jury demand in a 35 U.S.C. § 271(e)(2) action in which defendant had asserted counterclaims for a declaration of invalidity and noninfringement). The *Glaxo v. Apotex* court relied on *Lockwood* for the proposition that "in 18th Century England, the validity of a patent where there was no claim for damages was equitable in nature and decided by the court." *Glaxo Group Ltd. v. Apotex, Inc.*, 2001 WL 1246628, at *5. The court distinguished the facts of *Lockwood* on the grounds that "plaintiff in the instant action has no ability to bring a legal claim, because defendant has not made, used, offered to sell, or sold a patented invention without authorization in violation of 35 U.S.C. § 271(e)." *Id.* The court concluded

> that an action brought pursuant to § 271(e)(2) is inherently equitable in nature, and that the remedies are limited accordingly. Therefore, as in *Tegal*, both prongs of the *Tull* test point to equity, and neither plaintiff nor defendant is entitled to a jury trial on any of the issues raised in this case. The mere fact that invalidity has been raised in a counterclaim rather than in an affirmative defense does nothing to change this characterization.

See also Glaxo Wellcome, Inc. v. Geneva Pharms. Inc., No. 97-CV-1921, 1997 WL 842429, 45 U.S.P.Q. 2d 1702, 1703 (D.N.J. Jul. 15, 1997) (holding that defendants' counterclaim for noninfringement was "'analogous to a traditional equitable remedy.' Such an action does not provide any Seventh Amendment right to jury trial and cannot sustain plaintiffs' jury demand") (internal citation omitted).

In short, the vast majority of district courts considering the issue have found no right to a jury trial in § 271(e)(2) actions.

2. The Federal Circuit Has Affirmed A District Court Ruling That There Is No Right To A Jury In 35 U.S.C. § 271(e)(2) Actions

Importantly, in *Glaxo v. Apotex*, the one District Court decision in which the jury issue was appealed and addressed by the Federal Circuit, the Federal Circuit affirmed the District Court's action in striking the jury demand.

The defendant in *Glaxo v. Apotex* petitioned the Federal Circuit for a writ of mandamus to direct the district court to vacate its order granting plaintiff's motion to strike defendant's jury demand. In a nonprecedential opinion, the Federal Circuit denied the writ. *In re Apotex*, No. 690, 2002 WL 31388364 (Fed. Cir. Oct. 9, 2002). Relying on both *Tegal* and *Lockwood*, the court reasoned that "the important question when deciding whether a party is entitled to a jury trial in an action involving a declaratory judgment claim is to determine what type of action would have been brought by the declaratory judgment defendant concerning the dispute." *Id.* at 903. The court found that "the nature of the underlying controversy is entirely equitable, involving only a controversy whether future acts should be enjoined." *Id.* The court held that in a 35 U.S.C. § 271(e)(2) case

> involving only possible future infringement, and in which there can be no damages because no infringing products have been marketed, the only relief that is before the district court is equitable in nature. Because the nature of the underlying controversy is entirely equitable, there can be no right to a jury trial.

Id.

The Federal Circuit's reasoning in *In re Apotex* was adopted by the court in *Ferring B.V. v. Barr Labs., Inc.*, 02-CV-9851 at *3 (S.D.N.Y. Mar. 2, 2004). In *Ferring*, a § 271(e)(2) action, the defendant asserted affirmative defenses and counterclaims of invalidity and noninfringement. The court granted the plaintiff's motion to strike Apotex's jury demand,

noting that "[t]he issues presented in [*In re Apotex*] are strikingly similar to those presented here." The court reasoned:

> The [*In re Apotex*] Court concluded that because the case involved "only possible future infringement" and there could be "no damages because no infringing products [had] been marketed" the only relief was equitable in nature. Similarly, here, no damages have been incurred nor could there be. The action involves "only possible future infringement" and therefore the only relief is equitable in nature.

Id. (internal citations omitted).

In sum, the majority of courts that have considered the issue have concluded that there is no right to a jury trial in 35 U.S.C. § 271(e)(2) actions in which the plaintiff seeks only prospective equitable relief, whether or not the defendant has asserted declaratory judgment counterclaims.[2] *See, e.g., Sanofi-Synthelabo*, 2002 U.S. Dist. LEXIS 15345, at *20 ("there is no right to a jury trial on counterclaims seeking a declaration of non-infringement or invalidity in a case commenced pursuant to § 271(e)(2) in the absence of actual damages"); *Biovail*, 2002 LEXIS 13502, at *8 ("Merely because some patent infringement actions may have been entitled to jury trials does not mean that all patent infringement actions have a right to a jury trial. No activities have yet occurred that would entitle the plaintiffs to damages in the present suit"); *Pfizer*, 2001 WL 477163, at *4 ("because the patentee in [a § 271(e)(2)] suit has no right to seek

[2] In a limited number of cases, and prior to the existence of binding precedent to the contrary, district courts granted jury trials ostensibly to avoid the risk of retrial following an appeal. *See Pechiney Rhenalu v. Alcoa Inc.*, No. 99-301-SLR, at *1 (D. Del. Dec. 22, 2000) (denying a motion to strike the patentee's jury demand on the grounds that "[a]lthough there is no binding precedent on this issue, the court is mindful of the Federal Circuit's reasoning in *In re Lockwood*, and does not wish to risk retrial based on this issue") (internal citations omitted); *Zeneca Ltd. v. Pharmachemie B.V.*, No. 96-12413-RCL, 1998 U.S. Dist. LEXIS 21499 (D. Mass. Oct. 8, 1998). These cases are distinguishable from the present case in that both were decided before the Federal Circuit's decisions in *Tegal* and *In re Apotex* and before the numerous recent district court opinions finding no right to jury trial in § 271(e) actions. In addition, *Pechiney Rhenalu* was not a § 271(e) action, but a declaratory judgment action in which the defendant-patentee sought a jury trial.

damages (it is limited by statute to only equitable relief), the patentee is not entitled to a jury trial in garden variety § 271(e)(2) infringement claims"); *Akzo Pharma Int'l B.V. v. Steris Labs., Inc.*, No. 93-1071, at *3 (D. Ariz. May 17, 1994) ("a prayer for injunctive relief does not warrant a demand for a jury"); *Abbott Labs. v. TorPharm, Inc.*, 309 F. Supp. 2d 1043, 1044 (N.D. Ill. 2004) (stating that a bench trial was conducted "because Abbott is seeking only equitable relief. Indeed, it could not seek damages, because TorPharm has not yet begun to market its generic substitute for Abbott's product"); *Glaxo Group Ltd. v. Dr. Reddy's Labs., Ltd.*, No. 01-4066 at *5 (JJL) (D.N.J. June 5, 2003) ("'[n]o jury trial should attach 'in the absence of any issue of past infringement for which damages could conceivably be recovered,'" quoting *Sanofi-Synthelabo*, 2002 WL 1917871, at *5); *Purdue Pharma L.P. v. Endo Pharms. Inc.*, No. 00 Civ. 8029 at *2 (S.D.N.Y. Mar. 4, 2003) (denying a jury trial on the grounds that "defendants failed to cite a single decision, let alone a controlling decision, that provides for jury trials on patent claims in ANDA cases where the plaintiff does not seek damages").

This Court should reach the same conclusion and strike Apotex's jury demand.

II. Apotex's Unenforceability Defense Should Be Stricken And Its Unenforceability Counterclaim Dismissed

A. Heightened Pleading Requirements Apply

Allegations of fraud, as well as allegations of inequitable conduct that charge the patentee with fraudulent behavior before the PTO, are subject to the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure and must be pled with particularity. *See* Fed. R. Civ. P. 9(b) ("[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity."); *Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Systems, LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003) (stating that a claim for inequitable conduct must be pled with particularity). Therefore,

"in pleading an inequitable conduct claim, a party cannot merely rely on vague allegations that broadly recite the elements of fraud, but instead must either specify the time, place, and content of any alleged misrepresentations made to the PTO or otherwise 'give the defendant[] notice of the precise misconduct alleged.'" *Agere Sys. Guardian Corp. v. Proxim, Inc.*, 190 F. Supp. 2d 726, 733-34 (D. Del. 2002) (citations omitted); *see also Rentrop v. The Spectranetics Corp.*, No. 04 Civ. 0101, 2004 WL 1243608, at *2 (S.D.N.Y. June 4, 2004) (party pleading inequitable conduct "must allege facts giving rise to its claim of fraud on the Patent Office including the time, place and content of the alleged wrongful statements, the materiality of those statements and the facts giving rise to the inference that plaintiff intended to deceive the Patent Office."). This includes identifying any allegedly material prior art that the party contends was not disclosed to the PTO. *EMC Corp. v. Storage Tech. Corp.*, 921 F. Supp. 1261, 1263 (D. Del. 1996) (deeming inequitable conduct counterclaim that failed to disclose the relevant prior art insufficient under Rule 9(b)). The heightened pleading requirement of Rule 9(b) applies to Apotex's unenforceability allegations because, on the face of its Answer and Counterclaims, Apotex rests its unenforceability allegations on alleged fraud and inequitable conduct. (Answer and Counterclaims ¶¶ 31, 33, 59 and 61)[3]

The Federal Rules of Civil Procedure provide that a claim may be dismissed for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Failure to state a claim under Rule 12(b)(6) includes the failure to satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b). *See, e.g., Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783 n.5 (4th Cir. 1999) ("lack of compliance with Rule 9(b)'s pleading

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[3] Apotex also references fraud and inequitable conduct in its misuse allegation (Answer and Counterclaims ¶ 33) and unenforceability in its invalidity allegation (Answer and Counterclaims ¶¶ 28 and 49), apparently based on the same facts.

requirements is treated as a failure to state a claim under Rule 12(b)(6)"). The Federal Rules of Civil Procedure also authorize the Court to strike "from any pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). Under Rule 12(f), the Court may strike any defense that is insufficient as a matter of law. *See, e.g., France Telecom S.A. v. Novell, Inc.*, No. 102-437-GMS, 2002 WL 31355255, at *1 (D. Del. Oct. 17, 2002) (motion to strike will be denied only "if the defense is sufficient under the law").

This Court has not hesitated to grant motions to eliminate defective claims and defenses. *See, e.g., Sea Star Line, LLC v. Emerald Equip. Leasing, Inc.*, No. 05-245-JJF, 2006 WL 214206, at *2-*6 (D. Del. Jan. 26, 2006) (dismissing claims where party alleged no set of facts in support of those claims that would entitle it to relief); *Williams v. Potter*, 384 F. Supp. 2d 730, 734 (D. Del. 2005) (dismissing claims for failure to meet basic pleading requirements of Rule 8 where party's "vague and conclusory allegations" did not provide "fair notice of her claims and the grounds upon which these claims rest.").

B. Apotex's Unenforceability Allegations Fail To Satisfy Rule 9(b) and Rule 12(f)

Here, Apotex fails to plead its unenforceability allegations with the particularity required under Rule 9(b). The '194 patent issued in 1992, from an application that was filed with the PTO in 1988. Apotex, however, cites only two documents to justify its assertion that affirmative misrepresentations were made to the PTO during prosecution of the patent, both of which post-date the filing date of the U.S. application by nearly a decade or more – an article bearing on its face a 1997 copyright date and an Astelin® Nasal Spray package insert bearing on its face a revision date of May 2003. These documents do not, and cannot, support Apotex's assertion, as they did not exist when the alleged misstatements were made. Failing to reference any evidence from the relevant time – *before* the '194 patent issued – that was available to the

applicants and which might contradict statements in the specification or file history, Apotex's unenforceability allegations are merely "vague allegations" that fall short of the requirements of Rule 9(b).

Indeed, Apotex concedes that it requires further discovery to support its unenforceability allegations. However, a party may not use subsequent discovery to salvage a defective pleading. *EMC*, 921 F. Supp. at 1263-64. Indeed, one of the purposes of Rule 9(b) is to "eliminate fraud actions in which all the facts are learned after discovery." *Harrison,* 176 F.3d at 784; *see also Samsung Electronics Co., Ltd. v. Texas Instruments Inc.*, No. 3:96-CV-0001-P, 1996 WL 343330, at *3 (N.D. Tex. April 18, 1996) ("A general allegation of inequitable conduct should not be used as a launching pad for extensive or unwarranted discovery, and holding Plaintiff to the strictures of Rule 9(b) may assist in discouraging that practice."). Moreover, Apotex cannot circumvent the requirements of Rule 9(b) by including unenforceability as part of its misuse and invalidity allegations. *See, e.g., Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, No. C-95-3577-DLJ, 1996 WL 467293, at *11, *13 (N.D. Cal. July 24, 1996) (holding that unclean hands and misuse must be pleaded with particularity where these claims rest on allegations of inequitable conduct before the PTO). Therefore, the Court should strike Apotex's defenses and dismiss Apotex's counterclaims to the extent that they seek to have the '194 patent declared unenforceable. *Id.*

III. Apotex's Misuse Defense Should Be Stricken

To the extent that Apotex's misuse defense is based on alleged fraud or inequitable conduct, it should be stricken for failing to meet the heightened pleading requirements of Rule 9(b), as explained in Section II above. The remaining bases for Apotex's misuse allegation are MedPointe's: 1) commencement of this action, and 2) listing of the '194 patent in the Orange Book. However, both are protected activities that, as a matter of law,

cannot constitute patent misuse. Failing to properly plead any cognizable theory of patent misuse, Apotex's misuse defense should be stricken. *See Texas Instruments, Inc. v. Hyundai Electronics Industries, Co. Ltd.*, 49 F. Supp. 2d 893, 919 (E.D. Tex. 1999) (dismissing affirmative defense of patent misuse where party relied upon improper legal theory and alleged facts did not constitute patent misuse); *Townshend v. Rockwell Int'l Corp.*, No. C99-0400SBA, 2000 WL 433505, at *16 (N.D. Cal. Mar. 28, 2000) (dismissing patent misuse defense without leave to amend where defendants' allegations did not identify any anti-competitive conduct constituting patent misuse)

A. The Patent Act Excludes Patent Assertion From Misuse

MedPointe's commencement of this action cannot constitute patent misuse, as a matter of law, as the Patent Act provides in pertinent part that:

> No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: . . . (3) sought to enforce his patent rights against infringement or contributory infringement . . . .

35 U.S.C. § 271(d)(3); See also *Texas Instruments*, 49 F. Supp. 2d at 902-919 (E.D. Tex. 1999) (dismissing affirmative defense of patent misuse where conduct allegedly constituting patent misuse was specifically protected under 35 U.S.C. § 271(d)).

Section 271(d)(3) authorizes a patentee to enforce its patent rights against infringers and is a "clear expression of public policy approving such action." 5 Donald S. Chisum, *Chisum on Patents* § 17.05[3] at 17-93 (2005) (citations omitted); *see also Advanced Cardiovascular Sys., Inc., v. Scimed Sys., Inc.*, No. C-95-3577-DLJ, 1996 WL 467277, at *3 (N.D. Cal. July 24, 1996) ("[A] patent owner cannot be denied relief or found guilty of misuse simply by reason of seeking to enforce his or her patent."). In addition to being protected

activity, MedPointe's commencement of this action was clearly justified. Apotex apparently concedes infringement of the '194 patent – failing to raise noninfringement among its numerous defenses and counterclaims. Accordingly, MedPointe's commencement of this action does not constitute patent misuse.

B. Orange Book Submissions Do Not Qualify As Misuse

Patent misuse, a judicially-created extension of the equitable doctrine of unclean hands to the patent field, can be used by an accused infringer as an affirmative defense against an infringement claim. *See, e.g., Hoffman-La Roche Inc. v. Genpharm Inc.*, 50 F. Supp. 2d 367, 378 (D.N.J. 1999); *Windsurfing Int'l, Inc. v. AMF Inc.*, 782 F.2d 995, 1001 (Fed. Cir. 1986), *cert. denied*, 477 U.S. 905 (1986). To establish patent misuse, the accused infringer must "show that the patentee has impermissibly broadened the 'physical or temporal' scope of the patent grant with anti-competitive effect." *Windsurfing*, 782 F.2d at 1001 (quoting *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971)); *see also Advanced Cardiovascular Sys., Inc., v. Scimed Sys., Inc.*, No. C-95-3577-DLJ, 1996 WL 467277, at *4 (N.D. Cal. July 24, 1996) ("Defendant must state how plaintiff has attempted to overbroadly and impermissibly construe its patent such as to cause an anticompetitive effect..."). Apotex can make no such showing here based on MedPointe's listing of the '194 patent in the Orange Book, as the listing did not change its physical or temporal scope. The '194 patent covers the same methods of use, and expires on the same date, whether or not it is listed in the Orange Book.

In addition to failing to meet the general standard for patent misuse, Apotex fails to allege any of the specifically enumerated activities that have been held to constitute patent

misuse.[4] *See* 6 Chisum, § 19.04[3] at 19-451 (2005). The Federal Circuit has indicated its reluctance to expand the patent misuse doctrine to encompass acts beyond these specifically enumerated activities. *See C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1373 (Fed. Cir. 1998) (rejecting a claim of patent misuse based on grounds not listed in § 19.04[3] of Chisum, and concluding that "the body of misuse law and precedent need not be enlarged").

Moreover, MedPointe's listing of the '194 patent in the Orange Book is immune from liability. The Hatch-Waxman Act and corresponding regulations ***require*** MedPointe to submit patent information to the FDA for inclusion in the Orange Book:

> [An applicant for a New Drug Application] ***shall*** file [information regarding] any patent which claims the drug for which the applicant submitted the application or which claims a method for using such drug and with respect to which a claim for patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug."

21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53 (emphasis added).

The Supreme Court has established what has come to be known as the *Noerr-Pennington* doctrine, which makes petitioning the government immune from liability in all but the narrowest circumstances. *See, e.g., E.R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 140 (1961) ("The right of petition is one of those freedoms protected by the Bill of Rights, and we cannot, of course, lightly impute to Congress an intent to invade these

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[4] The enumerated activities are: (1) tying arrangements, requiring the purchase of unpatented goods for use with a patented apparatus or processes; (2) covenants prohibiting the production or sale of competing goods; (3) package licensing, conditioning the grant of one patent license upon the acceptance of another; (4) license agreements requiring the payment of royalties for use after the expiration of the patent; (5) conditioning the grant of a license upon agreement to pay royalties based on total sales, regardless of actual use of the patented product or process; (6) refusals to license a patent; (7) price fixing agreements; (8) territorial restrictions and resale restraints, attempting to restrict the disposition of a patented product after the first sale; (9) field of use restrictions and customer limitations; (10) grant-back clauses in patent licenses; (11) covenants restricting the licensor from granting additional licenses; and (12) refusals to use rights to a patent.

freedoms."); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965) (holding that efforts to influence public officials are not illegal); *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 122 (3d Cir. 1999), *cert. denied,* 528 U.S. 871 (1999) (noting that *Noerr-Pennington* immunity extends to petitioning of all types of government entities, including agencies) (citing *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972)).

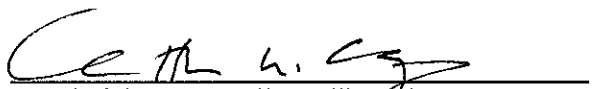
Under the *Noerr-Pennington* doctrine, the use of governmental process – such as in the submission of patent information to the FDA for listing in the Orange Book – is presumptively immune from liability unless it can be shown to be a "sham." *See Cheminor Drugs, Ltd. v. Ethyl Corp.*, 993 F. Supp. 271, 278 (D.N.J. 1998), *aff'd* 168 F.3d 119 (3d Cir. 1999), *cert. denied,* 528 U.S. 871 (1999). Establishing that conduct is a "sham" generally requires proof that: (1) the conduct was objectively baseless, in the sense that no reasonable person could realistically expect success on the merits; and (2) the conduct was an improper attempt to interfere with the business of a competitor through the use of governmental process, as opposed to the final outcome of that process. *Id.* at 278 (citing *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.,* 508 U.S. 49, 60 (1993)).

Apotex, however, does not, and cannot, allege that MedPointe's submission of information to the FDA regarding the '194 patent was a sham. MedPointe was required by law to list the '194 patent if it claimed a method of use described in its NDA and if MedPointe could reasonably assert the '194 patent against a party that engaged in the manufacture, use, or sale of the approved product. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53. Apotex does not, and cannot, allege that the '194 patent does not claim an approved method for using Astelin® Nasal

Spray.[5] Furthermore, Apotex's apparent concession of infringement confirms that MedPointe's submission of information regarding the '194 patent was based on an objectively reasonable belief that the patent could be infringed by the unauthorized manufacture, use, sale or offer for sale of a generic Astelin® Nasal Spray product. Accordingly, MedPointe's listing of the '194 patent in the Orange Book cannot, as a matter of law, constitute patent misuse.

CONCLUSION

For all the following reasons, MedPointe respectfully requests that the Court grant its Motion to Strike Apotex's Jury Demand, Strike Apotex's Affirmative Defense of Unenforceability, Dismiss Apotex's Counterclaim of Unenforceability, and Strike Apotex's Affirmative Defense of Misuse.



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Dated: May 4, 2006

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[5] The remedy for an improper Orange Book listing is an order requiring delisting of the patent, not a finding of misuse. *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I). If a patent does not claim the drug or approved method for using the drug for which it is listed, an ANDA applicant "may assert a counterclaim seeking an order requiring the [patent] holder to correct or delete the patent information." *Id.*

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 4, 2006, I electronically filed the foregoing motion, proposed order, and brief in support thereof with the Clerk of Court using CM/ECF which will send notification of such filing, and hand delivered to the following:

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I hereby certify that on May 4, 2006, I sent the foregoing motion, proposed order, and brief in support thereof by Federal Express, next business day delivery, to the following non-registered participant:

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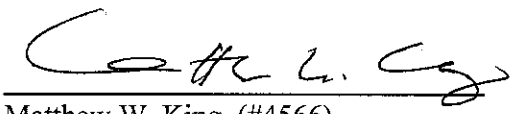

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